



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION 5  
77 WEST JACKSON BOULEVARD  
CHICAGO, IL 60604-3590

REPLY TO THE ATTENTION OF:

**JUL 27 2015**

**CERTIFIED MAIL NO.: 7009 1680 0000 7677 9364**  
**RETURN RECEIPT REQUESTED**

Mr. Terry C. Knight, Facility Manager  
Environmental, Health and Safety  
Bard Medical Division  
C. R. Bard, Incorporated  
One Rochester Medical Drive  
Stewartville, Minnesota 55976

Re: Notice of Violation  
Compliance Evaluation Inspection  
EPA I.D. No.: MND985688670

Dear Mr. Knight:

On May 6, 2015, a representative of the U.S. Environmental Protection Agency inspected Bard Medical— Site 2 facility (formerly Rochester Medical Corporation) located in Stewartville, Minnesota (Bard Medical Site 2). As a large quantity generator of hazardous waste, Bard Medical Site 2 is subject to the Resource Conservation and Recovery Act, 42 U.S.C. § 6901 *et seq.* (RCRA). The purpose of the inspection was to evaluate Bard Medical Site 2's compliance with certain provisions of RCRA and its implementing regulations related to the generation, treatment and storage of hazardous waste. A copy of the inspection report is enclosed for your reference.

Based on information provided by Bard Medical Site 2, EPA's review of records pertaining to Bard Medical Site 2, and the inspector's observations, EPA has determined that Bard Medical Site 2 has unlawfully stored hazardous waste without a permit or interim status as a result of Bard Medical Site 2's failure to comply with certain conditions for a permit exemption under Minn. R. 7045.0292, Subpart 1. EPA has identified the permit exemption conditions with which Bard Medical Site 2 was out of compliance at the time of the inspection in paragraphs 1 through 3, below.

Many of the conditions for a RCRA permit exemption are also independent requirements that apply to permitted and interim status hazardous waste management facilities that treat, store, or dispose of hazardous waste (TSD requirements). When a hazardous waste generator loses its



permit exemption due to a failure to comply with an exemption condition incorporated from Minn. R. 7045.0292, Subpart 1, the generator: (a) becomes an operator of a hazardous waste storage facility; and (b) simultaneously violates the corresponding TSD requirement. The exemption conditions identified in paragraphs 1 and 3 are also independent TSD requirements incorporated from Minn. R. 7045.0292, Subpart 1. Accordingly, each failure of Bard Medical Site 2 to comply with these conditions is also a violation of the corresponding requirements in Minn. R. 7045.0552 to 7045.0649 [40 C.F.R. Part 265].

#### **STORAGE OF HAZARDOUS WASTE WITHOUT A PERMIT OR INTERIM STATUS**

At the time of the inspection, Bard Medical Site 2 was out of compliance with the following large quantity generator permit exemption conditions. The permit exemption conditions identified below in paragraphs 1 and 3 are also independent TSD requirements violated by Bard Medical Site 2.

##### **Use and Management of Containers**

1. Under Minn. R. 7045.0292 Subpart 8 and 7045.0626 [40 C.F.R. §§ 262.34(c)(1)(i) and 265.173(a)], a large quantity generator may accumulate as much as 55 gallons of hazardous waste at or near the point of generation, which is under the control of an operator of the process generating the waste, if the container holding hazardous waste is closed during storage, except when it is necessary to add or remove waste. The lid, cap, hinge or closure device must be of sufficient strength and construction that when closed, the container will fully contain the hazardous waste. At the time of the inspection, Bard Medical Site 2 had not kept closed three (3) hazardous waste satellite accumulation containers.
2. Under Minn. R. 7045.0292 Subpart 8 [40 C.F.R. § 262.34(c)(1)(ii)], a large quantity generator may accumulate as much as 55 gallons of hazardous waste in containers at or near the point of generation, which is under the control of the operator of the process generating the waste, if he marks the containers with the words "Hazardous Waste" or with other words that identify the contents of the container. At the time of the inspection, Bard Medical Site 2 had not marked three (3) hazardous waste satellite accumulation containers with the words "hazardous waste" or with other words that identified the contents of the container.

##### **Contingency Plan**

3. Under Minn. R. 7045.0292 subpart 1 (G) and 7045.0572 Subpart 6 (D) [40 CFR §§ 262.34(a)(4) and 265.54 (d)], a large quantity generator must immediately amend the contingency plan, whenever the list of emergency coordinators changes. At the time of the inspection Bard Medical had not amended the contingency plan, when the list of emergency coordinators changed.



By failing to comply with the conditions for a permit exemption, above, Bard Medical Site 2 became an operator of a hazardous waste storage facility, and was required to obtain a Minnesota hazardous waste storage permit. Bard Medical Site 2 failed to apply for such a permit. Bard Medical Site 2's failure to apply for and obtain a hazardous waste storage permit violated the requirements of Minn. R. Minn. R. 7001.0500 and 7001.0050 [40 CFR §§ 270.1(c), and 270.10(a) and (d)]. Any failure to comply with a permit exemption condition incorporated from Minn. R. 7045.0292, Subpart 1 is also an independent violation of the corresponding TSD requirement.

At this time, EPA is not requiring Bard Medical Site 2 to apply for a Minnesota hazardous waste storage permit so long as it immediately establishes compliance with the conditions for a permit exemption outlined in paragraphs 1 through 3, above.

According to Section 3008(a) of RCRA, EPA may issue an order assessing a civil penalty for any past or current violation, requiring compliance immediately or within a specified time period, or both. Although this letter is not such an order or a request for information under Section 3007 of RCRA, 42 U.S.C. § 6927, we request that you submit a response in writing to us no later than 30 days after receipt of this letter documenting the actions, if any, which you have taken since the inspection to establish compliance with the above conditions. You should submit your response to Diane M. Sharrow, U.S. EPA, Region 5, 77 West Jackson Boulevard, LR-8J, Chicago, Illinois 60604." EPA is also suggesting that Bard Medical Division inform the Minnesota Pollution Control Agency of any change in ownership and facility name.

If you have any questions regarding this letter, please contact Ms. Sharrow, of my staff, at 312.886.6199 or at [Sharrow.Diane@epa.gov](mailto:Sharrow.Diane@epa.gov).

Sincerely,



Gary J. Victorine, Chief  
RCRA Branch

Enclosure

cc: John Elling, Minnesota PCA ([john.elling@state.mn.us](mailto:john.elling@state.mn.us))





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION 5  
77 W. JACKSON BOULEVARD  
CHICAGO, IL 60604

COMPLIANCE EVALUATION INSPECTION REPORT

INSTALLATION NAME: Bard Medical Division – Site 2

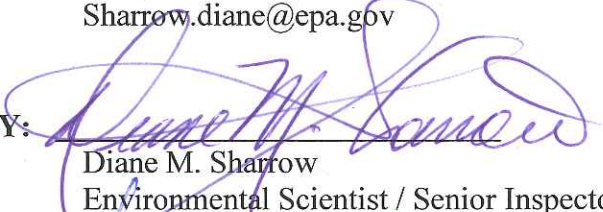
EPA ID No.: MND 985 688 670

LOCATION ADDRESS: 1500 2<sup>nd</sup> Street NW, Stewartville, Minnesota 55976

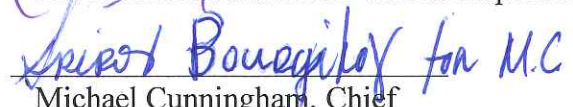
NAICS CODE(S): 339112 Surgical and Medical Instrument Manufacturing

DATE OF INSPECTION: 6 May 2015

EPA INSPECTOR: Diane M. Sharrow  
Environmental Scientist / Senior Inspector  
Mail Code LR-8J  
Land and Chemicals Division  
RCRA Branch  
Compliance Section 1  
(312) 886-6199 Direct  
(312) 692-2906 Facsimile  
Sharrow.diane@epa.gov

PREPARED BY:   
Diane M. Sharrow  
Environmental Scientist / Senior Inspector

6-15-15  
Date

APPROVED BY:   
Michael Cunningham, Chief  
Compliance Section 1  
RCRA Branch

7-10-2015  
Date



## INTRODUCTION

### Purpose of Inspection

The purpose of the inspection was to conduct an unannounced Compliance Evaluation Inspection (CEI) at Bard Medical Division - Site 2 (formerly Rochester Medical Corporation – Site 2 (Bard Medical Site 2), located at 1500 Second St., NW, Stewartville, Minnesota. The CEI was conducted to evaluate Bard Medical Site 2's compliance with provisions of the Resource Conservation and Recovery Act (RCRA), and the state and federal regulations related to the generation, treatment and storage of solid waste, hazardous waste, used oil and universal waste.

### Background

A CEI to evaluate compliance with certain provisions of the RCRA, including those regulations related to the generation, treatment and storage of hazardous waste, was last conducted at Bard Medical Site 2 by staff of the Minnesota Pollution Control Agency (Minnesota PCA) on December 29, 2011. Bard Medical Division is a unit of C. R. Bard, Incorporated and Site 2 manufactures male anatomical catheters. C. R. Bard, Incorporated recently purchased Rochester Medical Corporation.

Bard Medical Site 2 notified the United States Environmental Protection Agency (EPA) that it was a large quantity generator (LQG) of hazardous waste on or about February 23, 1994. Bard Medical Site 2 is currently operating as a LQG and most recently identified their waste codes as D001, D018, D028, D040, F003 and F005 on their 2014 Annual Report.

## OPENING CONFERENCE

I arrived at Bard Medical Site 2 at approximately 12:30 P.M. CST. I noted that the signage at 1500 Second Street, North West indicated "BARD" and not Rochester Medical (see Photographs 1 and 2). I parked my vehicle and attempted to find an entrance. I could not find an entrance with a lobby or receptionist, but found what appeared to be an employee entrance. I pushed a buzzer and a man opened the door. I presented my enforcement credentials and explained that the purpose of my visit was to conduct an unannounced CEI. The man asked me to wait and he entered what appeared to be an office area of the building. A woman then exited the office area and asked me to go to the Bard Medical Division Main Office at One Rochester Medical Drive. I left Bard Medical Site 2 and drove approximately a half mile north to One Rochester Medical Drive (see Photograph 3). I noted that there was a Bard Medical facility immediately to the east and assumed that it was Site 1.

I entered the building and pushed a buzzer. A man opened the door and introduced himself as Mark Thorburn, Director of Manufacturing and Distribution. I presented my enforcement credentials and explained that the purpose of my visit was to conduct an unannounced CEI. He explained that Terry Knight, the Environmental Health and Safety Manager had left to go to a medical appointment, but that he had been contacted by cellular telephone and that he was on his way back to the facility.



Mr. Thorburn and I exchanged business cards and he invited me to join him in a conference room. Mr. Thorburn recorded my enforcement credentials number F17235 and expiration date of August 31, 2017. We were soon joined by Shelley Aswegan, Training Coordinator and Rob Anglin, Vice President of Quality. I exchanged business cards with Ms. Aswegan as well as Mr. Anglin and presented my enforcement credentials. I explained that the purpose of my visit was to conduct an unannounced CEI. Mr. Thorburn connected Terry Moore, the head of Bard Medical Division Environmental Health and Safety who is located in Georgia on a conference telephone. I told Mr. Moore that I had presented my enforcement credentials to the representatives of Bard Medical.

I explained to the group that the CEI would include a Records Review as well as a Visual Site Inspection (VSI). I briefly summarized for the group the records that I would be reviewing during the Records Review portion of the CEI, and provided Mr. Thorburn with the U.S. EPA OECA Small Business Information Sheet. I informed the group that Bard Medical Site 2 could claim any information gathered during the CEI as Confidential Business Information (CBI) including: verbal information, documents and photographs.

The group explained that some of the records I wished to review were at Bard Medical Site 2, but that they could access some of the records from the One Rochester Medical Drive site as well. We agreed that I would review records until Mr. Knight arrived, and then Mr. Knight would escort me on the VSI portion of the CEI at Bard Medical Site 2. We then relocated to another conference room and Mr. Moore was disconnected.

In the second conference room, the group summarized Bard Medical Site 2's operations and indicated that the facility accumulates and stores hazardous waste in satellite and storage containers, with less than 90 day storage, generates used oil that goes to OSI, and generates universal waste fluorescent bulbs and batteries that go to Greenlight. Ms. Aswegan provided a handout (see attached) that summarized Hazardous Waste generated On-Site at Bard Medical Site 2.

## **RECORDS REVIEW**

During Phase 1 of the Records Review, I asked the group of representatives from Bard Medical if they could provide me with a copy of a site diagram that I could use during the VSI. Ms. Aswegan provided me with a copy of the Evacuation Plan from the Bard Medical Site 2 Contingency Plan (see attachment), dated March 5, 2014. I reviewed the Contingency Plan and noted that Mr. Knight was the emergency coordinator and that Jeff Ambourn, Shelly Aswegan and Andy Dejorden were the alternates. Ms. Aswegan stated that Mr. Ambourn had resigned and had been replaced by Mr. Thorburn, but the Contingency Plan had not yet been updated or shared with local authorities. She stated that the March 5, 2014 Contingency Plan had been distributed to the local authorities including the volunteer Olmstead County Fire Department and the Olmstead County Sheriff Department.



I reviewed training records and noted that Bard Medical uses a consultant to conduct training and that recent training had been conducted on January 4, 2012; March 7, 2012; March 7, 2013; and March 5, 2014. I asked if training had been conducted in 2015, and Ms. Aswegan stated that it had not yet occurred. I also asked about Mr. Thorburn's training and was told he had received on-the-job training when he started.

Mr. Knight joined the group at this time, and I presented my enforcement credentials to Mr. Knight. We agreed that I would continue the Records Review at Bard Medical Site 2 after I completed the VSI. I explained to Mr. Knight that I would be taking photographs, but that I would then let him know if I was going to take a photograph so that: 1) he could also take a photograph; and 2) he could inform me whether my photograph captured images or information that Bard Medical Site 2 wished to protect by asserting a claim of CBI. Bard Medical Site 2 did not make a CBI claim for any of the information gathered during the CEI. However, Mr. Knight did say that electronic devices that were not grounded could not be used in certain places at Bard Medical Site 2.

### **VISUAL SITE INSPECTION**

I left One Rochester Medical Drive and drove my vehicle back to Bard Medical Site 2. When we arrived, Mr. Knight introduced me to Howard Donohue III, Dipline Technician and Roger Hanson, 2<sup>nd</sup>/3<sup>rd</sup> Shift Production Supervisor. Before I started the VSI I also asked Mr. Knight to verify that my personal safety equipment (steel-toed boots, hardhat, earplugs, and safety glasses with side shields) was adequate. Mr. Knight indicated that I would need to wear a hair net and a grounding device, and provided me with both. I donned the hair net and attached the grounding device to my boots.) I then started the VSI at 2:15 P.M. CST.

We walked past the dip lines where Mr. Knight indicated there was a containment system under each dip line. We then entered the Flammable Storage Room where hazardous waste is stored. I noted two spill kits and thirty-six 55-gallon drums (see Photograph 4). I observed that the drums were all labeled as hazardous waste, closed, grounded, dated and organized in four rows with nine drums to a row. I also noted that the hazardous waste was identified included still bottoms, lab waste, paper waste (dirty rags and towels and cardboard with adhesive material), and xylene contaminated with adhesive material. I also observed that some of the drums had labels with the word "empty". Mr. Knight said that they were left on after use. I suggested that they be removed or crossed out so to avoid confusion. We then left the Flammable Storage Room and proceeded to the Chemical Storage and the Mixing Room.

Mr. Knight pointed out that Bard Medical Site 2 has a sprinkler system and I observed fire extinguishers throughout the facility. I asked about emergency communication devices and Mr. Knight indicated that in addition to phones Bard Medical was going to also employ a "Man Down" device from Grace Industries. Outside the Chemical Storage Room, we removed all electrical devices including cellular telephones and my camera prior to entering.



I noted that Chemical Storage and the Mixing Room (CSM Room) are essentially one room with a wall mid-room that partially extends from the south wall halfway to the north wall. I looked out the exit door on the south side and noted a thermal oxidizer. Inside the Mixing Room I observed a parts washer on the east wall as well as a paper compactor. On the east side of the “half-wall” I saw a satellite accumulation hazardous waste container marked “oily waste” on top, and observed that it was not closed in that the lid was not secured (latched). I cautioned Mr. Knight that containers must be closed when waste was not being added or removed. On the west side of the half wall on in the Chemical Storage part of the room, I observed one satellite accumulation container marked hazardous waste. Along the south and west side of the Chemical Storage Room I observed a Still Unit with a container on the east side marked hazardous waste still bottoms. In front of the Still Unit (north) there were two empty containers and in front of the two empty containers were two containers that were not marked hazardous waste that were approximately half filled and were not closed. I told Mr. Knight that satellite accumulation containers need to be marked as hazardous waste and closed when hazardous waste was not being added or removed. Mr. Knight noted that the Still Unit was made in Italy and was being replaced with a newer and more efficient Still Unit from Germany in July 2015.

During the VSI portion of the CEI, I took one photograph with my Canon Power Shot A2500 digital camera, with 16 megapixel resolution. I took three photographs prior to the VSI. These photographs are attached to this inspection report and are true and representative of the conditions I observed on the date of the CEI.

## RECORDS REVIEW

After the VSI, we exited the manufacturing portion of Bard Medical Site 2 and entered the office area. Mr. Knight directed me to a vacant office where I review additional records not available earlier at One Rochester Medical Drive. During Phase 2 of the Records Review I reviewed: 1) hazardous waste profiles 117409, 137153, 140638 and 141301; 2) hazardous waste manifests; and 3) land disposal restriction certifications (see Minn. R 7045.1390).

During my review of hazardous waste manifests I noted that Bard Medical Site 2 used the transporter Hydrite WID084106137 and WRR WID990829478 as a TSD. I noted that hazardous waste manifested offsite has included: 1) waste flammable solids such as toluene and petroleum distillates (F005, D001, D018, D028 and D040); 2) waste flammable liquid toluene and xylene (F005, F003, D001; and 3) waste flammable liquid heptanes and toluene (F005 and D001). I also noted that hazardous waste manifests and land disposal restriction certifications were being signed by Bob Dynhard (now retired per Mr. Knight) and John Swain.

I reviewed weekly hazardous waste inspections that were completed every Thursday by Ms. Aswegan, and noted that her inspections noted corrections to be made if needed. Mr. Knight also indicated used oil and universal waste at Bard Medical Site 2 is stored in the Maintenance Area on the east side of the manufacturing facility and that there are two drums of lamps currently in use for storage; one drum for 4 foot lamps and one drum for 8 foot lamps. As we exited the vacant office, Mr. Knight pointed out that their current Minnesota License was posted on a display board.



## **CLOSING CONFERENCE**

At the end of the VSI and Phase 2 of the Records Review, I returned to One Rochester Medical Drive in my vehicle. At approximately 3:30 P.M. CST, I conducted a brief closing conference in Mr. Thorburn's office with Mr. Thorburn, Mr. Anglin and Mr. Knight. Mr. Moore participated via a conference line as did Kevin Phoenix, director of Global and Worldwide Facilities. I ensured that Mr. Phoenix was aware that I had presented my Enforcement Credentials. I explained that I would review my notes, checklist and photographs and make a compliance decision. I also explained that I would send a letter to Bard Medical Site 2, along with the inspection report, checklist and photographs. I then concluded the CEI. I returned to my vehicle and departed Bard Medical Division and One Rochester Medical Drive 4:00 P.M. CST.

## **Attachments**

Inspection Checklist  
Photographs (4)  
Evacuation Plan  
Hazardous Waste Generated On-Site



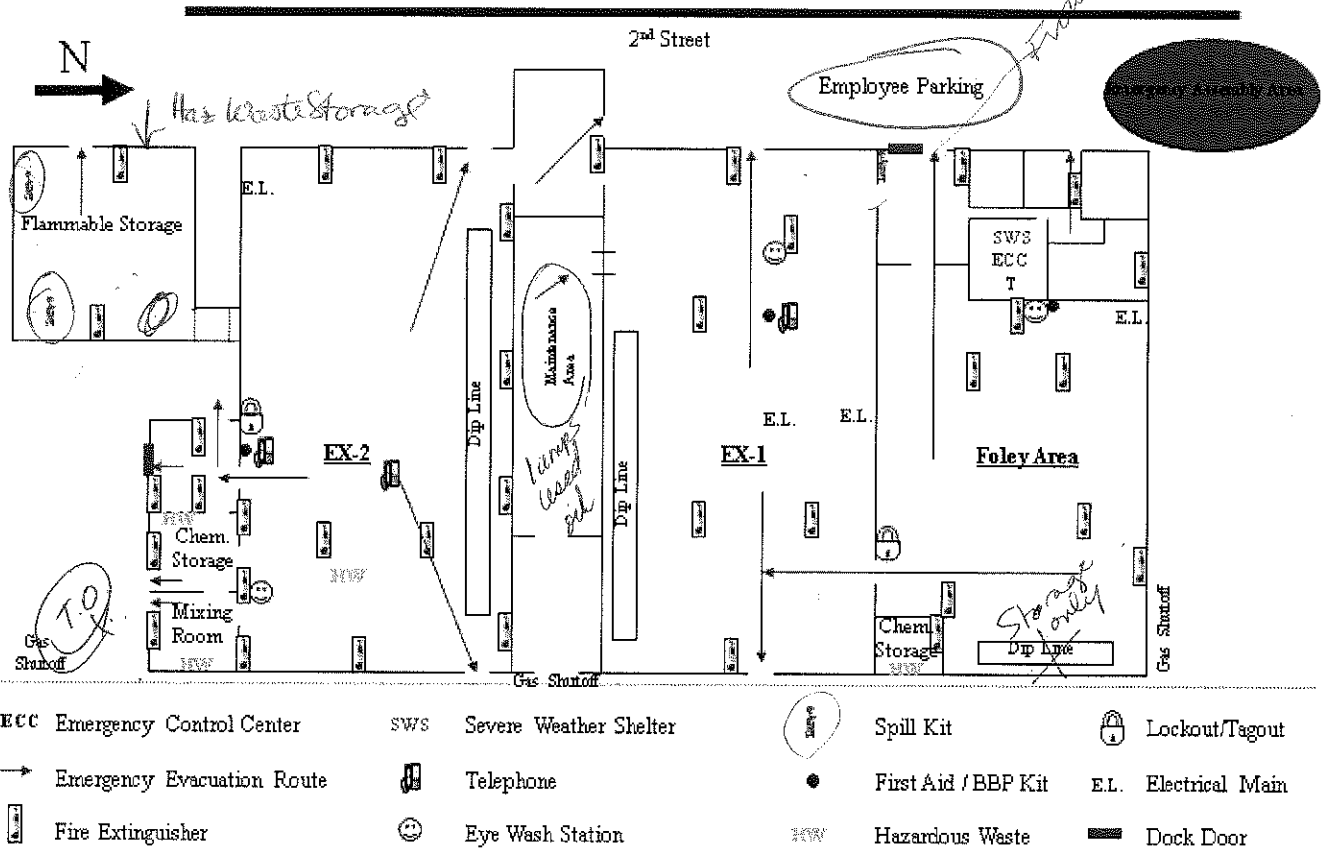
Rec'd 5/6/15 from  
Rochester Medical by  
Jm8

## EVACUATION PLAN

### Rochester Medical

1500 2nd Ave. NW

Emergency Evacuation Facility Map





*Rec'd 5/6/15 from  
Rochester Medical  
by JMS*

## **HAZARDOUS WASTE GENERATED ON-SITE**

EPA ID# ROME02

<b>WASTE STREAM</b>	<b>WASTE ID #</b>	<b>ANNUAL GENERATION</b>	<b>MAX AMOUNT STORED</b>
Lab Waste (Toluene, Heptane)	D001, F005, D018	25,000 – 35,000 pounds	Several Drums
Paper Waste (toluene, petroleum distillates)	D001, F005, D018	4,000 Pounds	Several Drums
Fluorescent Bulbs	Universal	Varies	Varies
Used Oil	Used Oil	55 Gal.	55 Gal
Batteries	Universal	Varies	Varies

**\*\* F & D Class Hazardous Wastes generated on-site are stored in the Chemical Storage rooms and in the Chemical Mixing or Chemical Storage Rooms (areas are marked on maps).**



*Rochester Medical Corporation Site 2*  
*(Bard Medical Division)*  
*EPA ID: MND 985 688 670*



PHOTOGRAPH 1 of 4: 1500 Second St. Signage

*Photographer D. Sharrow with Canon Power Shot A2500 Digital Camera, 16 megapixel resolution.*

**Rochester Medical Corporation Site 2**  
**(Bard Medical Division)**  
**EPA ID: MND 985 688 670**



PHOTOGRAPH 2 of 4: 1500 Second St.

**Photographer D. Sharrow with Canon Power Shot A2500 Digital Camera, 16 megapixel resolution.**

**Rochester Medical Corporation Site 2**  
**(Bard Medical Division)**  
**EPA ID: MND 985 688 670**



PHOTOGRAPH 3 of 4: One Rochester Medical Drive

**Photographer D. Sharrow with Canon Power Shot A2500 Digital Camera, 16 megapixel resolution.**

**Rochester Medical Corporation Site 2**  
**(Bard Medical Division)**  
**EPA ID: MND 985 688 670**



PHOTOGRAPH 4 of 4: Hazardous Waste Container Storage

**Photographer D. Sharrow with Canon Power Shot A2500 Digital Camera, 16 megapixel resolution.**

# Minnesota Pollution Control Agency

Report Title: Large Quantity Generator (LQG) Compliance Evaluation Inspection Checklist

Preferred ID: MND85688670

Regulated Party: Rochester Medical Corporation Site 2

Date: 5/6/15

Inspector:  
Diane Shannon

(Name Change? not. MPCA?)  
[Bard Medical Division]

## G1: Licensing / EPA / Permits

Rule	Requirement	Compliance Status	Remarks
7045.0221	Has Regulated Party obtained a generator identification number?	✓	
7045.1020 A	Metro Area - Does the Regulated Party have an approved license?	N/A	
7045.0225 1	Outstate - Does the site have a current hazardous waste generator license?	✓	
7045.0230 1, B	Outstate - Did the Regulated Party include all hazardous waste streams on its license application?	✓	
7045.0225 2	Is the Regulated Party's license displayed in a public area at the licensed site?	✓	
7001.0520 1, A	Does the Regulated Party operate as a TSD without a permit?	N/A	
MS 116.48 1	Are aboveground tanks >500 G registered with the MPCA? Are underground tanks registered with the MPCA?	not checked ✓	

## G1: Waste Evaluation

Rule	Requirement	Compliance Status	Remarks
7045.0214 1	Have wastes been evaluated within 60 days of the date they were initially generated?	✓	
7045.0294 3	Are test result records of waste analyses kept for 3 years from the last time the waste was sent to a TSDF (on- or off-site)?	✓	

MS

### G1: General Management for Generators

Rule	Requirement	Compliance Status	Remarks
7045.0208 1	Is hazardous waste properly disposed of?	✓	
7045.0208 1, E	Does the Regulated Party comply with the POTW requirements for sewer hazardous waste?	N/A	
7045.0294 5	Are the required records (training, analytical results, inspection reports, license renewal app, exception reports, manifests) located at the licensed site and available for inspection?	✓	
7045.0568 1	Have emergency response arrangements been made with local authorities and outside providers? (fire, police, local hospital, emergency responders)		
7045.0568 3	Has the Regulated Party documented in its operating record the arrangements made with local emergency authorities?		
7045.0655 3, A	If there is an elementary neutralization unit, a pretreatment unit and/or waste water treatment unit, does the owner or operator conduct timely inspections of the unit(s) for malfunction, deterioration, operator error and discharges?	N/A	
7045.0655 3, B	If there is an elementary neutralization unit, a pretreatment unit and/or waste water treatment unit, does the Regulated Party follow a written inspection schedule for inspection of all monitoring equipment, safety and emergency equipment, security devices and operating and structural equipment?	N/A	
7045.0655 3, E	If there is an elementary neutralization unit, a pretreatment unit and/or waste water treatment unit, are all applicable inspection (and repair) records (logs) kept for at least 3 years and available on-site?	N/A	
7045.0845	Does the Regulated Party properly manage used oil?		
7045.0895 4	Has used oil accepted from or given to another business to be burned for energy recovery been tested to determine that it is on-specification?	N/A	

*MS*

### G1: General Management for Generators

Rule	Requirement	Compliance Status	Remarks
7045.0855 4, C	Does the Regulated Party keep records of every shipment of used oil leaving the generator site for at least three years?	✓	
7045.0805	Does the Regulated Party properly manage used oil-contaminated waste?	✓	
7045.0855 4, C	Does the Regulated Party keep records of every shipment of used oil-contaminated waste leaving the generator site for at least three years?	✓	
7045.0990	Is the Regulated Party properly managing used oil filters?	✓	
7045.0990 3, C, 3	Does the Regulated Party keep records of all used oil filters taken off-site by used oil-filter transporters for at least three years?	✓	

### G1: Preparedness & Prevention

Rule	Requirement	Compliance Status	Remarks
7045.0566 2	Is hazardous waste managed to prevent or minimize releases?	✓	
7045.0566 3, A	Is a suitable alarm or communication system in place to provide emergency instructions to Regulated Party personnel?	✓	<div style="border-left: 2px solid black; padding-left: 10px; margin-left: 20px;"> Contractor, tests + maintains see below Man Down System </div>
7045.0566 3, B	Is emergency communication equipment available to summon outside emergency responders?	✓	
7045.0566 3, C	Is fire control equipment, decontamination equipment, and spill control equipment available?	✓	

*MS*

### G1: Preparedness & Prevention

Rule	Requirement	Compliance Status	Remarks
7045.0566 3, D	Is water available in adequate volume for fire control (i.e., firehose, sprinkler system and/or foam equipment) ?	✓	
7045.0566 4	Is emergency equipment tested and maintained?	✓	Contractor Maintain
7045.0566 5	Does the Regulated Party provide all personnel involved in hazardous waste being poured, mixed, spread, or otherwise handled with immediate access to an internal alarm or emergency communication device?	✓	
7045.0566 6	Is aisle space adequate for emergency operations (like fire fighting, spill cleanup, etc)?	✓	
7060.0600 2	Has the Regulated Party discharged waste or pollutants to the unsaturated zone, through spills, dumping, sewerage or other means?	N/A	
7045.0275 2	If the Regulated Party had a release to the environment did the Regulated Party immediately notify the agency?	N/A	
7045.0275 3	If the Regulated Party has had a release, did the Regulated Party recover as rapidly and as thoroughly as possible, any HW that has leaked, spilled, or otherwise escaped a container?	N/A	
7045.0855 2, D	Upon detection of a release of used oil to the environment (not originating from a UST) did the Regulated Party stop the release, contain the released used oil, clean up and manage properly the released used oil and other materials contaminated with used oil, and repair or replace any leaking used oil storage equipment prior to returning it to service to prevent future releases?	N/A	

*ans*

### G1: Storage Requirements

Rule	Requirement	Compliance Status	Remarks
7045.0292 1, F	Are hazardous waste containers & tanks properly labeled with the words "Hazardous Waste" and a description that clearly identifies their contents to employees and emergency personnel?		✓ 1 satellite accum. cont.
7045.0292 1, C	Are hazardous waste containers and tanks labeled with the waste accumulation start date and is it visible for inspection? OR Is the accumulation start date recorded in a clear and legible log for non-shipping containers or tanks?	✓	
7045.0292 1, A	Has the generator stored HW for more than 90 days beyond the waste accumulation start date?	N/A	
7045.0292 1, D	Are hazardous waste storage areas (outdoors) protected from unauthorized access and inadvertent damage from vehicles & equipment?	N/A	
7045.0292 1, E	Are hazardous waste containers that hold free liquid placed on an impermeable containment surface? If outdoors, is the surface curbed?	✓	
7045.0626 2, A	Are hazardous waste storage containers in good condition and leakproof?	✓	
7045.0626 2, B	Are there suitable leakproof covers for the hazardous waste containers?	✓	
7045.0626 3	Are hazardous waste storage containers compatible with the waste stored in them?	✓	
7045.0626 4	Are hazardous waste storage containers closed? Are waste containers which can be degraded when exposed to moisture or sunlight covered by an overhead roof or other suitable covering that does not hide the labels?	yes yes N/A	
7045.0626 5	Are weekly inspections of hazardous waste containers and their storage areas conducted AND documented?	✓	

*MS*

## G1: Storage Requirements

Rule	Requirement	Compliance Status	Remarks
7045.0626 6	Are incompatible wastes adequately separated?	✓	
7045.0292 8, B,2	Are satellite accumulation containers properly labeled with "Hazardous Waste" and a clear description of their contents?	✓	1 not labelled
7045.0292 8, C,2	For satellite accumulation containers, if located away from the point of generation, are they inspected weekly, and are written records kept?	N/A	
7045.0292 8, D,1	For satellite accumulation containers, is fill date marked on the containers?	✓	
7045.0292 8, D,2	For satellite accumulation containers, are they moved within 3 days of fill date to storage area?	✓	
7045.0855 2, C	If used oil is stored, is it stored in containers or tanks that are in good condition, stored on impermeable surfaces, kept closed, and labeled "Used Oil" (including tanks, containers and piping)?	used oil	
7045.0855 2, C	Are wastes contaminated with used oil stored in containers or tanks that are in good condition, on impermeable surfaces, closed, and labeled "Used Oil" or "Used Oily Waste"?		
7045.0990 3, A	If used oil filters are stored, are they stored in containers that are closed, leakproof and labeled "Used Oil Filters"?		
273.14 (a)	Are universal waste batteries (each battery), or a battery storage container, labeled with: "Universal Waste-Battery(ies)," or "Waste Battery(ies)," or "Used Battery(ies)"?		
273.13 (a)	Are universal waste batteries (lead acid, NiCad, etc) that show evidence of leakage, spillage, or damage stored in a closed, structurally sound, compatible container?		

*DNB*

### G1: Storage Requirements

Rule	Requirement	Compliance Status	Remarks
273.14 (e)	Are containers of universal waste lamps labeled with: "Universal Waste-Lamp(s)" or "Waste Lamp(s)" or "Used Lamp(s)"?	}	
273.13 (d)	Are universal waste lamps stored in closed containers that are structurally sound, adequate to prevent breakage, and compatible? Do containers lack evidence of leakage, spillage, or damage?		
273.13 (c)	Is mercury containing equipment stored in closed containers that are structurally sound, compatible with the contents of the device? Does the container lack evidence of leakage, spillage, or damage?	}	
273.14 (d)	Is mercury containing equipment (i.e. each device) or a container in which the equipment is contained labeled with: "Universal Waste - Mercury Containing Equipment," "Waste Mercury-Containing Equipment," or "Used Mercury -Containing Equipment"?		

### G1: Manifests

Rule	Requirement	Compliance Status	Remarks
7045.0261 1	Are shipments of hazardous waste made without using a manifest? (exceptions for VSQGs)	N/A	
7045.0261 7	Do manifests contain ALL of the following?: Manifest document number, generator data, transporter data, facility data, waste data, required signatures & dates, and a 24 hour emergency number. (document problem manifests in remarks and Description of Violation)	✓	
7045.0265 1, D	Have copies of manifests signed by the generator and transporter been sent to the MPCA within five working days of the initial transporter's acceptance of the waste?	✓	
7045.0265 4, A	Have copies of manifests signed by the facility been sent to the MPCA within 40 days of the acceptance of the waste by the facility?	✓	

*DMS*

### G1: Manifests

Rule	Requirement	Compliance Status	Remarks
7045.0298	If applicable, has the generator submitted to the MPCA an exception report for manifest copies not received back from the TSDF within 45 days of the date the waste was initially shipped?	N/A	
7045.0294 1	Are signed facility copies of manifests available for review for 3 years from the date material was accepted by the initial transporter?	✓	
7045.0302 1	If Regulated Party exports hazardous waste, are all applicable rules being complied with? (notification, consent, EPA acknowledgement of consent, shipping papers or manifests, etc)	N/A	

### G1: Land Disposal Restrictions

Rule	Requirement	Compliance Status	Remarks
268.7 (a), (2)	For waste or contaminated soil that does not meet treatment standards, has the Regulated Party sent a one-time land disposal restriction notification to the receiving treatment or storage facility? Is a copy of the notification available at the Regulated Party's site? Have new notifications been sent when there are changes in waste streams and to any new receiving facilities?	N/A	

### G1: Personnel Training

Rule	Requirement	Compliance Status	Remarks
7045.0558 1	Have employees that manage hazardous waste completed a hazardous waste training program?	✓	
7045.0558 2	Does the Regulated Party have a hazardous waste program director trained in hazardous waste management procedures?	✓	Contractor
7045.0558 3	Does the training program include hazardous waste management and emergency response procedures relevant to the positions held by facility personnel?	✓	Cont-plan

*AMS*

### G1: Personnel Training

Rule	Requirement	Compliance Status	Remarks
7045.0558 4	Are new employees trained in hazardous waste management within 6 months of hire or transfer?	✓	
7045.0558 5	Is refresher training regarding the management of hazardous waste provided at least once per calendar year?	✓	Contractor
7045.0558 6, A	Does the Regulated Party maintain training records which include a job title for each position at the facility related to hazardous waste?	✓	
7045.0558 6, B	Do the records include a job description for each position related to hazardous waste?	✓	See Cont. Plans Human Resource (Records)
7045.0558 6, C	Is a written description of the type and amount of training (initial & continuing) documented for each position related to hazardous waste?	✓	
7045.0558 6, D	Has the Regulated Party kept records that document that the initial training and annual review training has been given?	✓	
7045.0558 7	Have training records been maintained for lifetime of facility (or 3 years after an employee leaves.)?	✓	

### G1: Contingency Plan

Rule	Requirement	Compliance Status	Remarks
7045.0572 2	Does the Regulated Party have a contingency plan?	✓	
7045.0574 1	Does the Regulated Party have an Emergency Coordinator on-site or on-call, and does s/he have authority to act (commit resources?)	✓	

*DMS*

# G1: Contingency Plan

Rule	Requirement	Compliance Status	Remarks
7045.0572 4, A	Does the contingency plan specify employees' emergency response actions?	✓	
7045.0572 4, C	Does the plan describe arrangements agreed to with local emergency responders?	*	Not specific. Needs names of local authorities
7045.0572 4, D	Does the plan include up-to-date name, address and Home and Work phone numbers for emergency coordinators?	*	See p. 5 of CP alternate emerg coord not updated
7045.0572 4, E	Does the contingency plan include an up-to-date emergency equipment list?	✓	
7045.0572 4, F	Is there an evacuation plan for employees that includes signals used to begin evacuation, and primary and alternate evacuation routes?	✓	
7045.0572 5, A	Is a copy of the contingency plan maintained on-site?	✓	no documentation in
7045.0572 5, B	Have copies of the contingency plan been submitted to local authorities and emergency response teams?	↓	
7045.0572 6	Has the contingency plan been amended when necessary? (rule change, emerg. eqpt change, process change, emerg. coord. change, plan failed)	*	alter emerg. Coord not specified

Notes: NAICS: 33 9112 Surgical & Medical Instrument Manufacturing  
(Male Catheters)

Not - 2/23/99 last Insp. 12/29/11